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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/789,436

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William R. Patterson

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FOLEY & LARDNER LLP
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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

05/29/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/789,436	Applicant(s) PATTERSON ET AL.	
	Examiner JAMES W. ROGERS	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21,22 and 30-45 is/are pending in the application.
- 4a) Of the above claim(s) 42-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21,22 and 30-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/18/2008 has been entered.

Election/Restrictions

Applicant's election with traverse of the species of the ratio of EVOH to fumed silica in a range of about 1.09 to 1 in the reply filed on 03/17/2008 is acknowledged. The traversal is on the ground(s) that the entire claimed range can be searched without undue burden. This is not found persuasive because the species would require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph, thus presenting a burden on the examiner. Claims 42-44 are withdrawn for pertaining to a non-elected species.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-22,30-41 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically claims 21 and 41 now recite a weight ratio of EVOH polymer to fumed silica, however the examiner could not find support within the paragraphs cited by applicants [000117] and [000118] for the claimed ratios. There is support for a ratio of about 1.3 to 1 but there is no support for a ratio of about 1.33 to about 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 21-22, 30-36, 38-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Porter et al. (US 2004/0156781 A1).

Porter discloses polymer-embolizing compositions for filling cavities of the body and kits comprising such compositions. See abstract. The composition comprises 3-12 % by weight of polymer (preferably EVOH), 20-55% contrast agent (including tantalum which is claimed), about 1-12% rheological modifier (preferably fumed-silica), solvent (preferably DMSO) and other ingredients such as surfactants, the weight percents of the above ingredients are within the ratios and percents claimed by applicants. See [0062],[0067],[0074], [0079],[0091],[0096] and claims. Regarding the limitations in the claims on the viscosity of the composition, since the compositions have the same ingredients and the same concentrations it is inherent that the compositions will have the same properties such as viscosity since they are essentially the same. Where the claimed and prior art products are identical or substantially identical in structure or

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composition, or are produced by identical or substantially identical processes, a prima facie case or either anticipation or obviousness has been established, thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. Regarding the new limitation within claim 21 on the weight ratio of EVOH to fumed silica, the examiner considers about 1.33:1 to about 1.0:1 to read on the ratio of EVOH and fumed silicon described in Porters experimental section where the weight ratio is 0.9:1, 15g EVOH:16.5 g fumed silica. See [0120]-[0122]. The examiner considered the recitation of about to mean 1.33:1 to $1:1 \pm 0.17$, thus any value of EVOH from 0.83 to 1.5 compared to 1 unit of fumed silica would be within applicants claimed range. The examiner found the average difference between 1.0 to 1.33 to find the value of 0.17 ($1.33 - 1 = 0.33$, $0.33/2 = \sim 0.17$). Furthermore the ratios of claims 21 and 41 would have been obvious to one of ordinary skill in the art from the disclosure of Porter since the amounts of EVOH and fumed silica can overlap applicants claimed range, for instance both EVOH and fumed silica can be present in an amount of 12% each, a ratio of 1:1 within applicants claimed range for claim 21. It is considered ordinary and routine practice by the examiner for one of ordinary skill in the art to adjust the amounts of biopolymer to rheological modifier when making an embolic composition in order to control the viscosity of the composition. See [0089]-[0090] As described within Porter the amount of biocompatible polymer and rheological agent are adjusted to permit the composition to exhibit rheological behavior. See [0003] Regarding the limitation in claims 34-35 and 40 that the kit also comprises a vascular prosthesis, Porter teaches that a microballoon (considered by the examiner to

be a vascular prosthesis) may be employed in combination with the embolic composition to attenuate blood flow. Regarding claim 38 that states the kit included directions for use, it is obvious that a composition intended to be injected into the body to form a solid mass such as an embolism would come with directions for its use.

Claims 21-22, 30-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Porter et al. (US 2004/0156781 A1, '781 from hereon) in view of Porter (US 2003/0039696 A1, '389 from hereon), cited previously.

'781 is disclosed above. Porter is silent on the use of a coil in conjunction with the embolic composition as required in dependent claim 37.

'389 discloses embolic compositions with non-cyanoacrylate rheology modifying agents. The rheological modifying agent can impart an apparent viscosity of between 25 cP and 2000cP. See [0014]. Among the rheological agents that could be selected is fumed-silica in amounts between about 0 to about 75 percent. See [0048] and [0052]. Any suitable device for administering a liquid composition such as a microcatheter could deliver the composition. The invention could also employ any method of using a variety of commercially available endoluminal devices which act to confine the occlusive composition within a lumen, including catheters, catheter wires, catheter coils, stents and catheter balloons. See [0019]. The above endovascular devices can cause a temporary or permanent obstruction to movement of the occlusive composition outside of the vascular or aneurismal cavity.

It would have been obvious to one of ordinary skill in the art at the time of applicants claimed invention to deliver the embolic composition of '781 with the catheter coil of '389 and had a reasonable expectation of success since both references are clearly related to the same field of endeavor, embolic compositions. Thus one of ordinary skill in the art would expect that a method of delivering an embolic composition in one reference such as the catheter coil of '389 could be used to deliver the embolic composition of the other reference '781 with no change in the respective functions of the two elements. Thus the claimed invention would have been *prima facie* obvious since all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618

Application Number 	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/789,436	PATTERSON ET AL.	
	Examiner	Art Unit	
	JAMES W. ROGERS	1618	